

Early Protection
Immunisation Programme
Information pack

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Why are we running this programme?

Influenza in 2010

In 2009 the World Health Organization declared a pandemic of Influenza A (H1N1). New Zealand experienced pandemic H1N1 influenza in winter 2009 and, based on the northern hemisphere's experience, another outbreak may occur in New Zealand in late March 2010 and peak in April. This is earlier than the usual influenza season. It is expected that pandemic H1N1 influenza will be the dominant strain during the 2010 influenza season.

Influenza Immunisation Programme 2010

The 2010 immunisation programme for influenza is due to commence in February. This year it is a two-stage programme, using two different vaccines:

- **Stage One** (Early Protection) runs from 1 February and uses a monovalent pandemic influenza vaccine, which only protects against pandemic H1N1 influenza.
- **Stage Two** is the usual Seasonal Influenza Immunisation Programme starting on 8 March. This stage uses the seasonal influenza trivalent vaccine, which protects against three strains of influenza, including the pandemic H1N1 influenza strain.

For more information on the Seasonal Influenza Immunisation Programme refer to the National Influenza Strategy Group's Influenza Kit and/or website www.influenza.org.nz.

Early Protection Programme

The Early Protection Programme offers early protection against pandemic H1N1 influenza to frontline health workers and those most at risk of more severe outcomes from pandemic H1N1 influenza. It has been implemented this year because the Ministry of Health expects a resurgence of pandemic H1N1 influenza may occur in autumn (around March) rather than the more usual influenza peak in winter and because there are risks around delays in producing seasonal influenza vaccine. The Ministry also expects that pandemic H1N1 influenza will be the predominant strain of influenza circulating in 2010. For more information on who is eligible for the Early Protection Programme see the Eligibility Criteria section.

The vaccine offered as part of the Early Protection Programme is the monovalent influenza vaccine, Celvapan[®], produced by Baxter Healthcare Limited. This vaccine protects against pandemic H1N1 influenza only.

New Zealand has a limited supply of this vaccine which is why the offer of pandemic vaccine is limited to specific priority groups. Most people will be able to access immunisation against pandemic H1N1 influenza through the usual seasonal influenza immunisation programme.

Two doses of the Celvapan[®] vaccine at least three weeks apart are required. It will be offered to the priority groups from 1 February 2010.

Recipients of monovalent pandemic vaccine will still need the seasonal influenza vaccine. While the pandemic H1N1 influenza strain is expected to be the most common influenza strain there may be other strains of influenza circulating. The seasonal influenza vaccine protects against three strains of influenza, including pandemic influenza.

District Health Boards

All District Health Boards (DHB) are running specific Early Protection immunisation clinics during February for those eligible for this programme. These may be in selected general practices, in other community settings, or in a hospital clinic.

To find out where your DHB has organised clinics and how you can access these clinics call 0800 IMMUNE (0800 466 863) or refer to the Early Protection Resources in this pack for your DHB contact person.

The clinic approach

The monovalent pandemic influenza vaccine comes in 10 dose vials, which need to be used within three hours. This means ten people must be immunised during this time.

Organising clinics and taking bookings is the most effective way to run the Early Protection Programme although it may mean that some people will have to travel further for this immunisation than they generally do for seasonal influenza immunisation.

Eligibility Criteria for the Early Protection Programme

The Ministry of Health purchased a limited quantity of monovalent pandemic influenza vaccine, enough for 150,000 people, based on a two-dose regime.

The Early Protection Programme will be focused on two priority groups:

1. frontline health workers, and
2. those at risk of more severe outcomes from pandemic H1N1 influenza.

Frontline health workers

The monovalent pandemic vaccine is being offered free to frontline healthcare workers who would be needed during a pandemic. This includes staff in general practice, emergency departments, intensive care units and others who may have direct contact with at-risk patients.

Note: DHBs are expected to cover the cost for administration of the vaccine.

It is important that frontline health workers are protected because they are the people we rely on to provide health services to our communities and, during a pandemic, health services are likely to have a bigger workload caring for people who are sick with the virus. They are also the people who, because of their work, are at higher risk of coming into contact with people who have been infected.

Individuals at risk of more severe outcomes from pandemic H1N1 influenza

The following people are *eligible for free immunisation* (both the cost of the vaccine and its administration) from 1 February 2010 (see Early Protection Resources in this Pack for more detailed information on the eligibility criteria):

- people under 65 years of age (including children) with certain conditions (as for seasonal influenza). For more information refer to the Clinical Guidelines section.
- pregnant women (for more information refer to the Clinical Guidelines section)
- people who are morbidly obese (for more information refer to the Clinical Guidelines section)
- all children aged from six months to their fifth birthday enrolled in eligible practices (For more information on Eligible Practices refer below and for information on immunising children refer to the Clinical Guidelines section)

Note: these individuals are also eligible for the free seasonal influenza vaccine (including administration) when it becomes available on 8 March 2010.

Individuals who are not eligible

Individuals who are 65 years and older

Usually people aged 65 years and older are considered at higher risk than younger people from influenza. However, older people are not expected to be at higher risk from pandemic H1N1 influenza as they seem to have some pre-existing immunity. They are not eligible for free immunisation as part of the Early Protection Programme – but they are eligible for the seasonal influenza immunisation programme and will be able to access influenza immunisation as per usual from 8 March onwards.

Private purchasers

The monovalent pandemic vaccine is not available for purchase.

Individuals who do not meet the Early Protection or Seasonal Influenza Immunisation Programme's eligibility criteria will be offered protection from pandemic H1N1 influenza via the usual seasonal influenza immunisation programme.

Eligible Practices

New Zealand and international evidence about the H1N1 pandemic shows that children under five years are more likely to be hospitalised or die than are older people. This is particularly notable in children of Māori and Pacific ethnicity. While no specific studies have yet been completed, we know from other respiratory infectious diseases that children who come from high deprivation areas are also more likely to be more severely affected.

Primary Health Organisation enrolment data provides a way to identify practices with a high proportion of children who are Māori, Pacific or who come from high deprivation areas. In these practices all children between the age of six months (the youngest age at which the vaccine is approved for use) and fifth birthday can get free immunisation. This method was chosen with the idea that these practice could then offer immunisation to all their young children without the need to discriminate on the basis of an individual's ethnicity or socio-economic status and keeping in mind the need to provide the vaccine through clinics.

As with any other method of selectively targeting a subsidy, some high needs children will not be eligible. However, it should be noted that all high risk children with chronic conditions such as asthma are already eligible for free influenza immunisation. Historically the uptake in young children has been very low.

For 2010 all children aged from six months to their fifth birthday who are enrolled in Eligible Practices are eligible for free (including administration) monovalent pandemic influenza vaccine and seasonal influenza vaccine.

Practices that have been designated as Eligible Practices have 50 percent or more of their enrolled children under six years identified as Maori, Pacific and/or from high deprivation areas.

Please contact your DHB to see if your practice is an Eligible Practice. The DHB contacts can be found in the Early Protection Resources in this pack.

Vaccine and Administration Details

The monovalent pandemic influenza vaccine

The monovalent pandemic vaccine offered for the Early Protection Programme is Celvapan[®] – produced by Baxter Healthcare Limited. For a detailed description refer to the Data Sheet in Early Protection Resources in this pack.

Celvapan[®] is an inactivated whole virion vaccine and is produced by growing the virus in cultured mammalian cells (Vero cell culture). The whole virus is then killed using formaldehyde and ultraviolet light and harvested to prepare the vaccine. The antigen used is the wild type A/California/07/2009 H1N1 strain.

Celvapan[®] is grown in mammalian cells and does not contain egg proteins. It is inactivated, does not contain live viruses, and cannot cause influenza.

Approval to use in New Zealand

Celvapan[®] vaccine was approved for use in New Zealand in January 2010. Celvapan[®] is indicated for prophylaxis of influenza in an officially declared pandemic situation in accordance with official guidance. It may be used in children from six months of age (in whom immunisation is considered necessary) and for adults. Refer to Early Protection Resources in this Pack for the Celvapan[®] Data Sheet and for more information on the approval to distribute vaccines process in New Zealand.

For more information on immunising pregnant women, the morbidly obese, children and co-administration with other vaccines refer to the Clinical Guidelines section.

Data sheet and consumer medicine information

Information about the known risks and benefits of Celvapan[®] are included in the Data Sheet, which is approved by Medsafe. Information aimed at consumers can be found in the consumer medicine information (CMI) for Celvapan.

The approved data sheet for the vaccine for Celvapan[®] is available from the Medsafe website at <http://www.medsafe.govt.nz/profs/Datasheet/dsform.asp> and in Early Protection Resources in this pack.

The consumer medicine information for Celvapan[®] is available from the Medsafe website at <http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>.

European Medicines Agency's summary of product characteristics – Celvapan – http://www.emea.europa.eu/humandocs/PDFs/EPAR/celvapan/spc/emea_spc_h982pu17en.pdf.

Dosage

Celvapan[®] is administered as two 0.5 ml doses administered at least three weeks apart for anyone aged six months and above.

For more information on immunising pregnant women, the morbidly obese, children and co-administration with other vaccines refer to the Clinical Guidelines section.

Presentation

Celvapan[®] comes in packs of 20 multi-dose vials of 5 ml suspension per pack. Each 5 ml vial should provide 10 doses (dose = 0.5 ml). Each pack should provide 200 doses. The pack size is 206 mm x 166 mm x 55 mm as per Figure 1 below.

Figure 1: Celvapan[®] vaccine box



Multi-dose vial training

A short multi-dose vial training module has been developed by the Immunisation Advisory Centre (IMAC) and can be accessed at <http://www.immune.org.nz> or call IMAC on 0800 IMMUNE (0800 466 863) for more information.

The Ministry expects that anyone who is vaccinating using Celvapan[®] in the Early Protection Programme should undertake this training.

Safety of monovalent pandemic vaccine

Safety data from clinical trials with Celvapan[®] and post-marketing safety data have been evaluated by Medsafe. These data demonstrated that the vaccine has an acceptable safety profile.

Clinical trial experience for children is limited. The analysis of safety data from a snapshot of the safety data base involving 146 subjects aged 6 months to 17 years of age (including 20 children aged 3-8 years and 20 toddlers and infants aged 6 months to 35 months) suggests a favourable safety profile with regard to systemic and local reactions. No serious adverse events were reported for any of the children up to 7 days after the first vaccination.

Systemic adverse reactions, the majority of which were mild, occurred in a small number of children in each of the three age groups vaccinated with either the 3.75 or 7.5µg vaccine dose.

Local reactions also occurred at a low frequency, with younger children and infants showing a tendency towards even lower rates of occurrence of local reactions. Note the sample size is small so this tendency is not conclusive.

Post-marketing experience is from across the UK and Europe where it is estimated at least 255,000 people, (including children between the ages of 6 months and 17 years) have been vaccinated with Celvapan[®]. The reports received remain consistent with the expected pattern of adverse effects for influenza vaccines. The safety data for children are similar to those available for adults. There is no reason to suspect the safety profile in New Zealand will be any different from that observed in Europe. The European Medicines Agency publishes a weekly report on safety and this can be accessed on <http://www.ema.europa.eu/pdfs/influenza/5580610en.pdf>

Experience with seasonal influenza vaccines has shown that changing the strain of virus in a vaccine does not substantially alter the safety profile of the vaccine.

The safety of all medicines and vaccines in New Zealand is monitored by the Centre for Adverse Reactions Monitoring (CARM), Medsafe, and the Medicines Adverse Reactions Committee (MARC).

As with any medicine or vaccine, suspected adverse reactions to the Celvapan[®] vaccine should be reported to CARM. For information on reporting to CARM refer to the *Immunisation Handbook 2006* Chapter 2 Processes for Safe Immunisation.

Effectiveness of the monovalent pandemic vaccine

Clinical data with Celvapan[®] demonstrates that, after two doses in 408 adults and elderly the immunogenic response (measured by rises in antibodies) measured are comparable to those observed with seasonal influenza vaccines.

Preliminary clinical data indicates that after the first dose of the vaccine in 101 children aged 9 – 17 years, 51 children aged 3-8years and 52 children aged 6 months to 3 years an adequate immunogenic response is demonstrated.

The vaccine meets all three internationally accepted immunogenicity criteria for influenza vaccines; the data therefore indicates that an adequate immune response is achieved.

Administering Celvapan[®]

Multi-dose vial

Celvapan[®] is supplied already mixed in a multi-dose vial. Each vial contains 10 (0.5 ml) doses.

Celvapan[®] must be allowed to reach room temperature and shaken before use. Once removed from the fridge, Celvapan must be used within three hours (even if the bung has not been pierced).

The vaccine should be administered as soon as possible after withdrawal from the vial.

Route of administration

The vaccine is given by intramuscular (IM) injection into the upper arm or anterolateral thigh.

Recommended needles and syringes for use with Celvapan[®]

Fixed 25 mm 25G needles and syringes will be supplied for use with Celvapan[®] and are recommended for administering this vaccine. These syringes and needles have been tested to ensure that the vaccine can be easily drawn up and that they are not significantly blunted by being used both for drawing up and injecting the vaccine.

If the vaccinator determines that the size of the patient or any other factor means that the fixed needle syringe is not suitable then a different syringe and/or needle can be used.

Adverse effects

As with any vaccine, Celvapan[®] can cause side effects in some people.

No serious adverse reactions were reported after the first or second vaccinations in the clinical trials.

The observed systemic and local reactions were similar to those generally experienced after vaccination with approved seasonal influenza vaccines.

The most common side effects are injection site reactions such as induration (hardening of the skin), erythema (redness), swelling and haemorrhage (bleeding) at the site of injection. Other common side effects include nasopharyngitis, headache, dizziness, vertigo, arthralgia (joint pain), myalgia (muscle pain), pharyngolaryngeal pain (sore throat), hyperhidrosis (sweating), pyrexia (fever), chills, fatigue, and malaise. These side effects will mainly be mild and last only two to three days. Some of these symptoms may be similar to a mild flu-like illness.

As with any medicine or vaccine, suspected adverse reactions to the Celvapan[®] vaccine should be reported to CARM. For information on reporting to CARM refer to the *Immunisation Handbook 2006* Chapter 2 Processes for Safe Immunisation.

Contraindications to Celvapan[®]

Specific contraindications include history of an anaphylactic (ie, life-threatening) reaction to any of the constituents or trace residues (eg, formaldehyde, benzonase, sucrose) of this vaccine.

General contraindications are the same as for all other National Immunisation Schedule vaccines (refer page 76 of the *Immunisation Handbook 2006*) and include an acute febrile illness.

Note: Those with egg allergy who are not able to have the seasonal influenza vaccine, which is egg based, can have Celvapan[®] because it does not contain any egg protein.

Precautions

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substance(s), to any of the excipients and to trace residues e.g. formaldehyde, benzonase, or sucrose.

Hypersensitivity reactions, including anaphylaxis, have been reported following Celvapan[®] vaccination. Such reactions have occurred both in patients with a history of multiple allergies and in patients with no known allergy.

Celvapan[®] should under no circumstances be administered intravenously or via an artery.

There are no data for Celvapan[®] administered through the subcutaneous route. Therefore, healthcare providers need to assess the benefits and potential risks of administering the vaccine in individuals with thrombocytopenia or any bleeding disorder that would contraindicate intramuscular injection unless the potential benefit outweighs the risk of bleeding.

The data sheet states some undesirable effects such as dizziness and vertigo may affect the ability to drive or use machines. Patients should be advised of this before they receive the vaccine.

Clinical Guidelines

Pregnant women

If pregnant women are infected by H1N1 influenza, they appear to be considerably more likely to develop severe disease, require hospitalisation or die as a result of complications compared with women who are not pregnant. The infection may also put the foetus and the newborn at risk. This risk is greatest in the second and third trimesters of pregnancy¹.

For this reason H1N1 influenza immunisation is strongly recommended for women who will be pregnant during the influenza season. The influenza vaccine is normally given in the 2nd and 3rd trimesters but may be offered to women who will be in the 1st trimester when influenza is circulating. For 2010, immunisation will be free to pregnant women wishing to have the influenza vaccine (both the Early Protection and the seasonal influenza programmes).

Celvapan[®] may be used in pregnant women.

There have been clinical trials that show the efficacy of Celvapan[®]. Although, as is the case with most trials, pregnant women were not included in the trials, there is no reason to think that the vaccine would not be as effective for women during pregnancy.

Because Celvapan[®] is a new vaccine there are no safety data specifically about use during pregnancy. However, previous influenza vaccines have been shown to be safe during pregnancy and Celvapan[®] has been used in pregnant women in other countries².

Pregnant women need to be informed of this information as part of the informed consent process.

Obesity

New Zealand and overseas experience suggests that there is an increased risk of complications from H1N1 influenza in those who are morbidly obese generally due to co-morbidities such as diabetes, asthma and renal disease³

The guideline for determining morbid obesity is BMI ≥ 35 in those over 18 years of age. Providers may use their discretion to determine the eligibility of their paediatric patients.

There are no particular safety issues about Celvapan[®] or seasonal vaccine use in obese individuals.

Children

New Zealand and international evidence about the H1N1 pandemic shows that children under five years are more likely to be hospitalised or die than are older people. This is particularly notable in children of Māori and Pacific ethnicity and those with chronic health conditions. While no specific studies have been undertaken, we know from other respiratory infectious diseases that children who come from high deprivation areas are also more likely to be more severely affected.

¹ World Health Organisation advice: "A fatal outcome was recorded in 2–9% of hospitalized patients. Pregnant women have a 10 times higher likelihood of requiring admission to an ICU compared with the general population; 7–10% of all hospitalized cases are women in their second or third trimester of pregnancy."

http://www.who.int/csr/disease/swineflu/meetings/sage_oct_2009/en/index.html

² Tamma PD, Ault KA, del Rio C, et al. Safety of influenza vaccination during pregnancy. *Am J Obstet Gyn.* 2009;201(6):547-552.2.

³ Guillermo Domínguez-Cherit; Stephen E. Lapinsky.; Alejandro E. Macias et al Critically Ill Patients With 2009 Influenza A(H1N1) in Mexico *JAMA.* 2009;302(17):(doi:10.1001/jama.2009.1536). 2009;302(17):1880-1887

As with adults children receiving the monovalent pandemic vaccine need two doses (0.5 ml) of vaccine at least three weeks apart.

Celvapan[®] may be used in children from six months of age and over. Influenza vaccines are not to be used in infants under six months of age.

Although there are limited data from clinical studies for the use of the Celvapan[®] vaccine in children, there are no reasons to doubt the vaccine's safety in children. It has been used for children in overseas pandemic immunisation programmes where the data raise no safety concerns. The Ministry is offering Early Protection immunisation for children under five years because a significant number of young children were hospitalised during the first wave of the pandemic in 2009, particularly those with chronic health conditions.

It is important that vaccinators give parents and guardians information both about the risk of influenza in their young child and about the limited safety information. Parents can then make a more informed choice.

The information pack includes a parent/guardian consent form for children.

Celvapan[®] and seasonal influenza vaccines

The pandemic H1N1 influenza strain is expected to be the most common influenza strain this year and both the monovalent and the seasonal vaccine will give protection against it.

However, there may be other strains of influenza circulating during 2010 and only the seasonal vaccine offers protection against them.

An individual who has had the monovalent vaccine during the Early Protection programme should also be offered the seasonal vaccine for full protection.

Co-administration

Celvapan[®] is recommended to be given separately from other vaccines.

Celvapan[®] is an inactivated vaccine and, from experience with influenza vaccine co-administration, it is not expected to have any safety or efficacy concerns. It should, however, be noted that adverse reactions may be intensified if Celvapan[®] is given with other vaccines.

If other vaccines are needed to be given at the same time the vaccines should be injected into separate limbs and accurately recorded in the patient's notes.

Informed Consent

The Ministry of Health recommends immunisation, however it is the patient's or their parent's/guardian's choice to accept immunisation.

Health professionals have legal obligations to obtain informed consent. The individual or guardian needs to understand the risks and benefits of vaccination, in order to give informed consent.

As part of the informed consent process the vaccinator should discuss with the individual or parent/guardian:

- What the risks are to them or their child if they contract pandemic influenza
- that the Celvapan® vaccine has been approved for use in New Zealand
- there is very little information available on the use of the Celvapan® vaccine in pregnant women, children under 9 years of age and co-administration with other vaccines
- it is the individual's or parents/guardians choice whether to be immunised against pandemic influenza or not.
- It is also the individual's or parents/guardians choice whether to vaccinate with the Celvapan vaccine or seasonal influenza vaccine
- That no identifiable information is being collected nationally about either the Celvapan or seasonal influenza vaccines.

Further information on informed consent can be found in the *Immunisation Handbook 2006 Chapter 2*.

Recording immunisation information

Accurate documentation is essential. If the vaccinator has not kept accurate clinical records, it is difficult to prove what action/care was or was not taken/delivered when the patient notes are held up for legal scrutiny.

The site of each Celvapan[®] dose, the vaccine product name and batch numbers, date given, and vaccinators name and signature should be recorded in the individual's records. If the vaccine is not being given by the individual's usual general practice then please ensure that a copy of the immunisation records are sent to their general practitioner.

Celvapan[®] vaccine consent forms are available which can assist in recording immunisation information and notifying the patient's general practitioner (if applicable). See the Early Protection Resources in this pack for copies of the Patient Consent Form and Parent/Guardian Consent Form for Children.

Note: The National Immunisation Register will not be collecting immunisation information for the Celvapan[®] vaccine.

Vaccine Ordering and Distribution

The Ministry of Health has a contract with Propharma for distribution of this vaccine. Propharma distributes the National Immunisation Schedule vaccines and has systems in place to protect the cold chain during distribution.

The Ministry has provided DHBs with Propharma order forms which they will distribute to hospital pharmacies and selected general practices to order the supplies they need to implement local immunisation arrangements. The DHB will stipulate the maximum volume of vaccine that can be ordered on each order form.

Propharma will deliver stocks of vaccine when they receive a faxed order on a Propharma order form which must include the Propharma account number.

DHB vaccine allocation

DHBs have been allocated a proportion of the available 300,000 doses of monovalent pandemic vaccine based on the percentage of New Zealand's population that they serve.

DHBs are responsible for local arrangements for immunisation and for managing vaccine distribution within their DHB so as to stay within their overall allocation.

Cold chain management

The Celvapan® vaccine needs to be transported and stored, prior to use, in its original packaging at 2°C to 8°C and protected from light. Do not freeze.

Cold chain standards for the monovalent pandemic vaccine are the same as for other influenza vaccines and are detailed on page 113 in the *Immunisation Handbook 2006*. Ask your local immunisation co-ordinator for advice on cold chain management.

Immunisation Benefit Claims

Funding

The Ministry of Health is providing monovalent pandemic vaccine and syringes with fixed needles to DHBs at no cost for the Early Protection Programme.

DHBs are responsible for ensuring that monovalent pandemic vaccine is available to the frontline healthcare workforce and those at risk from pandemic H1N1 influenza. The Ministry will cover the cost of the vaccine. DHBs are expected to cover the cost for administration of the vaccine.

DHBs are responsible for funding the delivery of the Early Protection Programme either through payment of the immunisation benefit or some other means. Providers are not entitled to charge patients either for the cost of the vaccine or for administering the vaccine.

Note: this vaccine is not available for private purchase or to those 65 years and over.

Immunisation benefit and payments

General practice may only claim the immunisation benefit for administering the Celvapan® vaccine to an individual who meets the Early Protection Programme's eligibility criteria for free vaccine and administration. This does not apply to frontline health workers as the administration cost will be covered by the DHB. For more information on who is eligible for free vaccine and administration refer to the Eligibility Criteria section.

There is a very limited timeframe to get changes for Seasonal Influenza 2010 into practice management systems. You should claim electronically as soon as the functionality of your PMS allows you to. Until that time you will need to submit claims manually. If you are claiming manually, you will need to obtain approval from your DHB to do so. The DHB letter supporting this may be sent with your first batch of claim forms. Manual claim forms can be ordered from Wickcliffe Ltd on 0800 259 138 - you will need to provide your payee number.

This vaccine will be claimed as a normal Influenza - i.e. tick IMFA, IMFV and put the indication and dose in the boxes beside Influenza - but there will be no vaccine reimbursement payment. Ministry payment systems will be set to automatically change to the seasonal influenza vaccine (including vaccine reimbursement) for claims with Date of Service from 8 March onwards.

Enquiries about claiming for this vaccination should be directed to the Sector Services Contact Centre on 0800 458 448

Monday – Friday 8:00am – 5:00pm, except Wednesday when the Contact Centre's hours are 9:30am – 5:00pm

Public Education Campaign

DHBs will run local media information programmes about the Early Protection Programme as they choose, but there will be no national public awareness campaign for this part of the influenza immunisation programme.

The Ministry's national public awareness and information campaign will start in March and will cover immunisation and infection control for seasonal influenza. This will be a comprehensive campaign particularly focused on increasing immunisation uptake in the six months to 64 years subsidised groups. The campaign will also provide messages on other pandemic H1N1 influenza protection such as the need to wash and dry hands thoroughly.

The catch phrase for the campaign is "**Don't let the flu get you**".

The campaign will incorporate:

- multimedia advertising
- resources for groups most at risk of severe outcomes from pandemic H1N1 influenza and priority audiences such as Maori and Pacific communities
- elements to facilitate primary health care services actively targeting and recalling their high risk patient populations.

It will also include some on-line and new media innovations to reach those in the younger age groups who are more at risk from pandemic influenza.

Advice and information to the health sector and for the majority of people will be available through the web; unpaid media (media releases and media conferences, social media such as Facebook and Twitter, blogs) and paid media.

The campaign success will be monitored with ongoing research.

Contact Information

For further information on the Early Protection Programme, please contact:

- Immunisation Advisory Centre on phone: 0800 Immune or email influenza@auckland.ac.nz or refer their website www.immune.org.nz
- your local DHB (see the Early Protection Resources in this pack for the contact person at your DHB).

For information on the Seasonal Influenza Immunisation Programme, please refer to the:

- National Influenza Strategy Group's Influenza Kit and/or website www.influenza.org.nz.

Early Protection Resources

DHB contacts

DHB		Name	email
Auckland		Andrew Coe	acoe@adhb.govt.nz
Bay of Plenty		Brian Pointon	Brian.Pointon@bopdhb.govt.nz
Canterbury	Main contact Primary care contacts	Bridget Lester Ann Fraser Diane Bos Bernadette Heaphy Jayne Thomas	Bridget.lester@cdhb.govt.nz ann_f@pegasus.org.nz diane_b@pegasus.org.nz bernadette@canterburyimms.co.nz jayne@canterburyimms.co.nz
Capital & Coast	Main contact Primary care contacts	Vicky Noble Helen Hartley Annette Nesdale	Vicky.Noble@ccdhb.org.nz helen.hartley@ccdhb.org.nz annette.nesdale@huttvalleydhb.org.nz
Counties Manukau	Main contact Primary care contact	Andrew Stacey Pam Montford	Andrew.Stacey@middlemore.co.nz Pam.Montford@cmdhb.org.nz
Hawkes Bay		Marg Dalton	Margaret.Dalton@hawkesbaydhb.govt.nz
Hutt Valley	Main contact Primary care contact	Lyn Taylor Tracey Green	Lyn.Taylor@huttvalleydhb.org.nz Tracey.Green@huttvalleydhb.org.nz
Lakes		Kath Erskine-Shaw	Kathleen.Erskine-shaw@lakesdhb.govt.nz
MidCentral		Barb Bradnock	barb.bradnock@midcentraldhb.govt.nz
Nelson Marlborough		Ed Kiddle	ed.kiddle@nmhs.govt.nz
Northland		Paul Baines	Paul.Baines@northlanddhb.org.nz
Otago		Rosie Simpson	rosie.simpson@otagodhb.govt.nz
South Canterbury		Jason Power	Jpower@timhosp.co.nz
Southland		Sandra Miller	sandra.miller@osdhbs.govt.nz
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Taranaki		Greg Simmons	Greg.Simmons@tdhb.org.nz
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Detailed eligibility criteria

People aged six months to 64 years with:

- cardiovascular disease (ischaemic heart disease, congestive heart failure, rheumatic heart disease, congenital heart disease and cerebrovascular disease)
- chronic respiratory disease (asthma if on regular preventive therapy; other chronic respiratory disease with impaired lung function)
- diabetes
- chronic renal disease
- any cancer, excluding basal and squamous skin cancers if not invasive
- other conditions (autoimmune disease, immune suppression, HIV, transplant recipients, neuromuscular and central nervous system disease, haemaglobinopathies, children on long term aspirin)
- pregnancy
- morbid obesity
- healthy children aged from six months to their fifth birthday enrolled in eligible practices.

Approval for use process

Medsafe is the part of the Ministry of Health responsible for ensuring the quality, safety and effectiveness of medicines and vaccines introduced into the New Zealand market. Medsafe is impartial and their advice is based solely on the extensive data that are supplied for each product.

Vaccines are granted consent for their use in New Zealand following a thorough review by Medsafe of the manufacturing standards and the quality of the final product, the level of immunity they induce and their safety profile. Where they are available, the product is assessed against internationally accepted criteria.

As part of the evaluation, any benefit of using the medicine is balanced against the risks posed by the disease and the safety profile of the vaccine. Based on the information provided in the application for approval the risk-benefit balance of Celvapan® is considered acceptable. This means that the benefits of using the product outweigh any associated risks.

For more information go to www.medsafe.govt.nz.

Celvapan Data Sheet

Pandemic influenza vaccine (whole virion, Vero cell derived, inactivated) suspension for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Whole virion influenza vaccine, inactivated containing antigen of pandemic strain*:

A/California/07/2009 (H1N1) 7.5 micrograms** per 0.5 mL dose.

* propagated in Vero cells (continuous cell line of mammalian origin)

** expressed in micrograms haemagglutinin.

This vaccine complies with the WHO recommendation and EU decision for the pandemic.

This is a multidose container. See *Nature and Contents of the Container* for the number of doses per vial.

For a full list of excipients, see *List of Excipients*.

PHARMACEUTICAL FORM

Suspension for injection.

The vaccine is an off-white, opalescent, translucent suspension.

CLINICAL PARTICULARS

Therapeutic indications

Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance.

Posology and method of administration

This pandemic influenza vaccine H1N1 has been authorised based on data obtained with a version containing H5N1 antigen supplemented with data obtained with the vaccine containing H1N1 antigen. The Clinical Particulars section will be updated in accordance with emerging additional data.

From clinical studies limited safety data are available for Celvapan (H1N1) in healthy adult and elderly subjects and in children (see *Special Warnings and Precautions for Use* and *Undesirable Effects*).

The decision to use CELVAPAN (H1N1) in each age group defined below should take into account the extent of the clinical data available with a version of the vaccine containing H5N1 antigen and the disease characteristics of the current influenza pandemic.

The dose recommendations are based on the available safety and immunogenicity data from clinical trials with CELVAPAN (adults, elderly and children and adolescents) and H5N1 (A/Vietnam/1203/2004; adults and elderly) where two doses of vaccine containing 7.5µg HA of either H1N1 or H5N1 were administered 21 days apart.

See *Special Warnings and Precautions for Use*, *Undesirable Effects* and *Pharmacodynamic Properties*.

Posology

Adults and elderly

One dose of 0.5 ml at an elected date.

A second dose of vaccine should be given after an interval of at least three weeks.

Children and adolescents aged 9 to 17 years of age

One dose of 0.5 ml at an elected date.

A second dose of vaccine should be given after an interval of at least three weeks.

Children aged 6 months to 8 years of age

Limited data are available in children 6 months to 8 years of age. Should vaccination be considered necessary, the experience with similarly constructed vaccines suggests that dosing in accordance with the adult dose may be appropriate.

The dosing used should take into account the extent of data and disease characteristics of the current influenza pandemic. Preliminary analysis of immunogenicity data from one clinical trial in children aged 6 months to 17 years suggests that an adequate immune response is achieved in this age group.

Children aged less than 6 months

Vaccination is not currently recommended in this age group.

For further information, see *Undesirable Effects* and *Pharmacodynamic Properties*.

It is recommended that subjects who receive a first dose of CELVAPAN, complete the vaccination course with CELVAPAN (see *Special Warnings and Precautions for Use*).

Method of administration

Immunisation should be carried out by intramuscular injection preferably into the deltoid muscle or anterolateral thigh, depending on the muscle mass.

Contraindications

History of an anaphylactic (i.e. life-threatening) reaction to any of the constituents or trace residues (e.g. formaldehyde, benzonase, sucrose) of this vaccine. However, if vaccination is considered necessary, it may be appropriate to give the vaccine, provided that facilities for resuscitation are immediately available in case of need.

See *Special Warnings and Precautions for Use*.

Special warnings and precautions for use

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substance(s), to any of the excipients and to trace residues e.g. formaldehyde, benzonase, or sucrose.

Hypersensitivity reactions, including anaphylaxis, have been reported following vaccination with Baxter's H5N1 vaccine (see *Undesirable Effects*). Such reactions have occurred both in patients with a history of multiple allergies and in patients with no known allergy.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

If the pandemic situation allows, immunisation shall be postponed in patients with severe febrile illness or acute infection.

CELVAPAN should under no circumstances be administered intravascularly.

There are no data with CELVAPAN using the subcutaneous route. Therefore, healthcare providers need to assess the benefits and potential risks of administering the vaccine in individuals with thrombocytopenia or any bleeding disorder that would contraindicate intramuscular injection unless the potential benefit outweighs the risk of bleedings.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

A protective response may not be induced in all vaccinees (see *Pharmacodynamic Properties*).

There are no safety, immunogenicity or efficacy data to support interchangeability of CELVAPAN with other H1N1 pandemic vaccines.

Interactions with other medicinal products and other forms of interaction

There are no data on co-administration of CELVAPAN with other vaccines. However, if co-administration with another vaccine is indicated, immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, published literature have reported false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the results.

Pregnancy and lactation

The safety of CELVAPAN in pregnancy and lactation has not been assessed in clinical trials. Animal studies with H5N1 strain vaccines (A/Vietnam/1203/2004 and A/Indonesia/05/2005) do not indicate direct or indirect harmful effects with respect to fertility, pregnancy, embryonal/fetal development, parturition or post-natal development (see *Preclinical Safety Data*). Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing CELVAPAN (see *Preclinical Safety Data*).

The use of CELVAPAN may be considered during pregnancy if this is thought to be necessary, taking into account official recommendations.

Effects on ability to drive and use machines

Some undesirable effects such as dizziness and vertigo may affect the ability to drive or use machines.

Undesirable effects

• Clinical trials with H5N1 mock-up vaccine

In clinical trials with the mock-up vaccine using an H5N1 vaccine strain (see *Pharmacodynamic Properties*) in 3576 subjects (3116 between 18 and 59 years old, and 460 aged 60 and above), the following adverse reactions were assessed as at least possibly related by the investigator. Most of the reactions were mild in nature, of short duration and qualitatively similar to those induced by influenza vaccines. There were fewer reactions after the second dose of the vaccine compared with the first dose. The most frequently occurring adverse reaction was injection site pain, which was usually mild.

Adverse reactions from clinical trials with the mock-up vaccine are listed below (see *Pharmacodynamic Properties* for more information on mock-up vaccines).

Adverse reactions are listed according to the following frequency.

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$).

Not known (cannot be estimated from the available data)

Infections and infestations

Common: nasopharyngitis

Blood and the lymphatic system disorders

Uncommon: lymphadenopathy

Psychiatric disorders

Uncommon: insomnia, restlessness

Nervous system disorders

Common: headache, dizziness

Uncommon: somnolence, dysaesthesia, paresthesia

Eye disorders

Uncommon: conjunctivitis

Ear and labyrinth disorders

Common: vertigo

Uncommon: sudden hearing loss

Rare: ear pain

Vascular disorders

Uncommon: hypotension

Respiratory, thoracic and mediastinal disorders

Common: pharyngolaryngeal pain

Uncommon: dyspnoea, cough, rhinorrhoea, nasal congestion, dry throat

Gastrointestinal disorders

Uncommon: gastro-intestinal symptoms (such as nausea, vomiting, diarrhoea and upper abdominal pain)

Skin and subcutaneous tissue disorders

Common: hyperhidrosis

Uncommon: rash, pruritus, urticaria

Musculoskeletal and connective tissue disorders

Common: arthralgia, myalgia

General disorders and administration site conditions

Very common: injection site pain

Common: pyrexia, chills, fatigue, malaise, induration, erythema, swelling and haemorrhage at the injection site

Uncommon: injection site irritation

Rare: injection site movement impairment

- Clinical Trials with CELVAPAN (H1N1)

Limited preliminary safety data after the first and second dose from clinical trials in adults aged over 18 years (N=408) and after the first dose in children aged from 9 to 17 years (N=101), 3 to 8 years (N=100) and 6 to 35 months (N=96) investigating two different dose levels (3.75µg or 7.5µg) of CELVAPAN H1N1 suggest a comparable safety profile with that reported for the influenza vaccines using a H5N1 strain.

Post-marketing surveillance

CELVAPAN H1N1

The following additional adverse reactions have been reported in the post-marketing experience in adults and children receiving CELVAPAN H1N1.

The frequency of these adverse reactions is not known.

Immune system disorder:

Anaphylactic reaction*, Hypersensitivity*

*Such reactions have been manifested by respiratory distress, hypotension, tachycardia, tachypnea, cyanosis, pyrexia, flushing, angioedema, and urticaria

Nervous system disorders:

Convulsion

Skin and subcutaneous tissue disorders:

Angioedema

Musculoskeletal and connective tissue disorders:

Pain in extremity

General disorders and administration site conditions

Influenza-like illness

Interpandemic trivalent vaccines

From post-marketing surveillance with other manufacturers' egg-derived interpandemic trivalent vaccines, the following serious adverse reactions have been reported:

Uncommon:

Generalised skin reactions

Rare:

Neuralgia, paraesthesia, convulsions, transient thrombocytopenia.

Allergic reactions, in rare cases leading to shock, have been reported.

Very rare:

Vasculitis with transient renal involvement.

Neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome.

Overdose

No case of overdose has been reported.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccines, ATC Code J07BB01

This section describes the clinical experience with the mock-up vaccine using a H5N1 strain (adults and elderly) following a two-dose administration and with CELVAPAN H1N1 (adults, elderly, children and adolescents) following a two-dose administration. The children and adolescent data are only available after the first dose at this time. Mock-up vaccines contain influenza antigens that are different from those in the currently circulating influenza viruses. These antigens can be considered as 'novel' antigens and simulate a situation where the target population for vaccination is immunologically naïve. Data obtained with the mock-up vaccine will support a vaccination strategy that is

likely to be used for the pandemic vaccine: clinical immunogenicity, safety and reactogenicity data obtained with mock-up vaccines are relevant for the pandemic vaccines.

Immune response against CELVAPAN H1N1

In a clinical study in adults aged 18 – 59 years (N=100) and elderly subjects aged 60 years and above (N=101) investigating the immunogenicity of the vaccine containing 7.5 mcg non-adjuvanted HA derived from strain A/California/07/2009 (H1N1) the seroprotection rate, seroconversion rate and seroconversion factor for anti-HA antibody as measured by hemagglutination inhibition (HI) were as follows:

HI Assay	21 Days After 1 st Dose			
	Total enrolled subjects		Seronegative subjects prior to vaccination	
	18 – 59 years (N=100)	60 years and above (N=101)	18 – 59 years (N=4)	60 years and above (N=4)
Seroprotection rate*	85.0%	72.3%	50.0%	75.0%
Seroconversion rate**	63.0%	33.7%	50.0%	75.0%
Seroconversion factor***	5.6	2.5	6.7	8.0

* HI titer \geq 40

** \geq 4-fold increase in HI titer or a reciprocal HI titer \geq 40 when there is no detectable titer at baseline

*** geometric mean increase

After the first vaccination the rate of subjects with neutralizing antibody titers \geq 40, seroconversion rate and seroconversion factor as measured by microneutralisation assay (MN) in adults aged 18 to 59 years and in elderly subjects aged 60 years and above were as follows:

MN Assay	21 Days After 1 st Dose			
	Total enrolled subjects		Seronegative subjects prior to vaccination	
	18 – 59 years (N=100)	60 years and above (N=101)	18 – 59 years (N=39)	60 years and above (N=34)
Seroneutralization rate*	87.0%	70.3%	74.4%	55.9%
Seroconversion rate**	80.0%	55.4%	84.6%	73.5%
Seroconversion factor***	21.3	5.0	28.8	7.1

* MN titer \geq 40

** \geq 4-fold increase in MN titer or a reciprocal MN titer \geq 40 when there is no detectable titer at baseline

*** geometric mean increase

In a clinical study in children and adolescents aged 9 – 17 years (N=52) investigating the immunogenicity of the vaccine containing 7.5 mcg non-adjuvanted HA derived from strain A/California/07/2009 (H1N1) the seroprotection rate, seroconversion rate and seroconversion factor for anti-HA antibody as measured by hemagglutination inhibition (HI) were as follows:

HI Assay	21 Days After 1 st Dose	
	Total enrolled subjects	Seronegative subjects prior to vaccination
	9 – 17 years (N=52)	9 – 17 years (N=3)
Seroprotection rate*	88.5%	66.7%
Seroconversion rate**	78.8%	66.7%
Seroconversion factor***	7.4	25.4

* HI titer \geq 40

** \geq 4-fold increase in HI titer or a reciprocal HI titer \geq 40 when there is no detectable titer at baseline

*** geometric mean increase

Immune response against the vaccine strain H5N1 A/Vietnam/1203/2004

The immunogenicity of the 7.5 μ g non-adjuvanted formulation of CELVAPAN (strain A/Vietnam/1203/2004) has been evaluated in two clinical studies in adults aged 18 – 59 years (N=312) and in elderly subjects aged 60 years and older (N=272) following a 0, 21 day schedule.

After primary vaccination the seroprotection rate, seroconversion rate and seroconversion factor for anti-HA antibody as measured by single radial haemolysis (SRH) in adults aged 18 to 59 years and in elderly subjects aged 60 years and above were as follows:

SRH Assay	18 – 59 years 21 Days After		60 years and above 21 Days After	
	1 st Dose	2 nd Dose	1 st Dose	2 nd Dose
Seroprotection rate*	55.5%	65.4%	57.9%	67.7%
Seroconversion rate**	51.3%	62.1%	52.4%	62.4%
Seroconversion factor***	3.7	4.8	3.6	4.6

* SRH area ≥ 25 mm²

** either SRH area ≥ 25 mm² if baseline sample negative or 50% increase in SRH area if baseline sample >4 mm²

*** geometric mean increase

After primary vaccination the rate of subjects with neutralizing antibody titres > 20 , seroconversion rate and seroconversion factor as measured by microneutralisation assay (MN) in adults aged 18 to 59 years and in elderly subjects aged 60 years and above were as follows:

Microneutralisation assay	18 – 59 years 21 Days After		60 years and above 21 Days After	
	1 st Dose	2 nd Dose	1 st Dose	2 nd Dose
Seroneutralisation rate*	49.4%	73.0%	54.4%	74.1%
Seroconversion rate**	39.1%	61.9%	14.3%	26.7%
Seroconversion factor***	3.4	4.7	2.1	2.8

* MN titre ≥ 20

** ≥ 4 -fold increase in MN titre

*** geometric mean increase

Cross-reactive Immune Response Against Related H5N1 Strains

In the phase 3 study in adults (N=265) and elderly subjects (N=270) after vaccination with the A/Vietnam/1203/2004 strain vaccine the rate of subjects with cross-neutralising antibodies as measured by MN (titre > 20) was as follows:

Tested against	18 – 59 years		60 years and above	
	Day 42 ^a	Day 180	Day 42 ^a	Day 180
Seroneutralisation rate*	35.1%	14.4%	54.8%	28.0%

* MN titre ≥ 20

^a 21 days after 2nd dose

In a dose-finding study in adults aged 18 – 45 years investigating various dose levels of adjuvanted and non-adjuvanted formulations of the A/Vietnam/1203/2004 strain vaccine the rates of subjects with neutralising antibody titres > 20 , seroconversion rates and seroconversion factor for cross-neutralising antibodies as measured by MN in subjects who received the 7.5 μ g non-adjuvanted formulation (N=42) were as follows:

Tested against	Strain A/Indonesia/05/2005	
	Day 42 ^a	Day 180
Seroneutralisation rate*	45.2%	33.3%
Seroconversion rate**	31.0%	21.4%
Seroconversion factor***	3.2	2.5

* MN titre ≥ 20

** ≥ 4 -fold increase in MN titre

*** geometric mean increase

^a 21 days after 2nd dose

Antibody Persistence and Booster Vaccination with Homologous and Heterologous Vaccine Strains

Antibody persistence after vaccination with the 7.5 μ g non-adjuvanted formulation of CELVAPAN (strain A/Vietnam/1203/2004) has been evaluated in two clinical studies in adults aged 18 – 59 years (N=285) and in one clinical study in elderly subjects aged 60 years and above (N=258) up to 6 months after the start of the primary vaccination series. The results indicate an overall decline in antibody levels over time. Data on later time points (months 12 and 24) are not yet available.

Seroprotection*/ Seroneutralisation rate**	18 – 59 years		60 years and above	
	SRH Assay	MN Assay	SRH Assay	MN Assay
Month 6	28.1%	37.9%	26.7%	40.5%

* SRH area \geq 25 mm²

** MN titre \geq 20

To date a booster vaccination with homologous and heterologous vaccine strains has been administered in the phase 3 study 6 months after primary vaccination with two doses of the A/Vietnam/1203/2004 strain vaccine. Two dose levels (3.75 μ g and 7.5 μ g) of both the A/Vietnam/1203/2004 and A/Indonesia/05/2005 strain vaccines were investigated for the booster vaccination.

Seroprotective titres as determined by SRH assay against the homologous vaccine strain (A/Vietnam/1203/2004) were observed in 65.5% of subjects aged 18 – 59 years and in 59.4% of subjects aged 60 years and older at 21 days after a booster vaccination with the 7.5 μ g dose of the A/Vietnam strain vaccine. Twenty-one days after a booster vaccination with the 7.5 μ g dose of the A/Indonesia/05/2005 strain vaccine a cross reactive response against the A/Vietnam strain was obtained in 69.0% of subjects aged 18 – 59 years and in 40.6% of subjects aged 60 years and older.

Antibody responses as measured by MN 21 days after the booster vaccination were generally slightly higher with the A/Indonesia/05/2005 than with the A/Vietnam/1203/2004 strain vaccine. Seroneutralisation rates (MN titre > 20) at 21 days after a booster vaccination with the 7.5 μ g dose of the A/Vietnam and A/Indonesia vaccines, tested against both the homologous and heterologous strains were as follows:

6-Month Booster	18 – 59 years		60 years and above	
	Vaccination with 7.5 μ g strain A/Vietnam			
Tested against	A/Vietnam	A/Indonesia	A/Vietnam	A/Indonesia
Seroneutralisation rate*	86.2%	65.5%	64.5%	54.8%
	Vaccination with 7.5 μ g strain A/Indonesia			
Seroneutralisation rate*	86.2%	93.1%	65.6%	71.9%

* MN titer \geq 1:20

Another study investigated a booster vaccination with 7.5 μ g of the heterologous A/Indonesia/05/2005 vaccine strain administered 12 – 15 months after an initial 2-dose priming with various dose levels of adjuvanted and non-adjuvanted formulations of the A/Vietnam/1203/2004 strain vaccine in subjects aged 18 – 45 years. In subjects who received the 7.5 μ g non-adjuvanted formulation for primary vaccination (N = 12) seroprotection rates as measured by SRH 21 days after the booster vaccination were 66.7% and 83.3%, and 100% and 91.7% of subjects achieved neutralising antibody titres > 20 when tested against the homologous A/Indonesia and the heterologous A/Vietnam strain, respectively.

No H5N1 clinical data have been generated in subjects below 18 years of age.

Information from non-clinical studies:

Baxter has produced an inactivated A/H1N1 wild-type whole virus candidate vaccine based on the A/California/07/2009 H1N1 influenza virus strain at 100 L GMP fermentation scale.

The immunogenicity of this pandemic A/H1N1 candidate vaccine, produced according to the final large scale GMP process established previously for H5N1 candidate vaccines, has been evaluated in a dose-response study in mice. Groups of ten female CD1 mice were immunized subcutaneously, twice, three weeks apart with one of six doses of pandemic H1N1 candidate vaccine (ranging from 3.75 μ g to 0.0012 μ g haemagglutinin). The pandemic H1N1 candidate vaccine was shown to be immunogenic in mice using the haemagglutination inhibition assay (HI) inducing titers up to 160 three weeks after the primary immunization and up to 5120 three weeks after the second dose.. A clear dose response was seen even after a single immunization and the anti-H1N1 antibody response was boosted further by a second immunization given three weeks after the first immunization. The effective dose 50% (that is, the dose inducing an HIA titre of at least 1:40 in half of the immunized mice) was found to be 300 ng for a single immunization and 7 ng for sera collected two weeks after a second immunization.

The protective efficacy of the mock-up vaccine using an H5N1 strain against morbidity and mortality induced by the infection with lethal doses of highly pathogenic avian Influenza H5N1 virus was assessed non-clinically in a ferret challenge model. Two studies have been performed using either the H5N1 A/Vietnam/1203/2004 or the A/Indonesia/05/2005 vaccine.

In one study, sixteen ferrets were divided into two cohorts and were vaccinated on days 0 and 21 with 7.5 μ g of the A/Vietnam/1203/2004 vaccine or were sham vaccinated. All ferrets were challenged intranasally on day 35 with a high dose of the highly virulent H5N1 virus strain A/Vietnam/1203/2004 and monitored for 14 days. Ferrets vaccinated with the 7.5 μ g dose of the A/Vietnam/1203/2004 vaccine demonstrated a high rate of seroconversion. The A/Vietnam/1203/2004 vaccine afforded protection against homologous challenge as evidenced by full survivorship, reduced weight loss, a less pronounced and shorter increase in temperature, a less marked reduction in lymphocyte counts and in reduction of inflammation and necrosis in brain and olfactory bulb in the vaccinated cohorts as compared to control animals. All controls animals succumbed to the infection.

In a second study, sixty-six ferrets were divided into 6 cohorts of 11 ferrets and were immunized on days 0 and 21 with 3.75 μ g or 7.5 μ g of the Indonesia vaccine or were sham vaccinated. The ferrets were challenged intranasally on day 35 with a high dose of either the clade 2 H5N1 virus A/Indonesia/05/2005 or the clade 1 H5N1 virus A/Vietnam/1203/2004

and monitored for 14 days. The A/Indonesia/05/2005 vaccine was shown to be efficacious with 100% survival, reduced incidence of fever, reduced weight loss, reduced virus burden, and reduced haematological (leukopenia and lymphopenia) changes in the vaccinated cohorts following homologous challenge. Similarly, the A/Indonesia/05/2005 vaccine was efficacious against a heterologous challenge, showing a vaccine dose dependent survivorship in the vaccinated cohorts as compared to the control cohort. Similar to the homologous challenge, vaccination against a heterologous challenge reduced virus burden, and reduced haematological (leukopenia) changes associated with highly pathogenic avian influenza infection.

Pharmacokinetic properties

Not applicable.

Preclinical safety data

Non-Clinical studies with mock-up vaccine using an H5N1 vaccine strain demonstrated alterations in liver enzymes and calcium levels in repeat dose toxicity studies in rats. Such alterations in liver function have not been seen to date in human clinical studies. Alterations in calcium metabolism have not been examined in human clinical studies.

Animal reproductive toxicology studies do not indicate harmful effects in regard to female fertility, embryo-foetal and pre- and post-natal toxicity.

PHARMACEUTICAL PARTICULARS

List of excipients

Trometamol
Sodium chloride
Water for injections
Polysorbate 80

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf-life

1 year
After first opening, the product should be used immediately. However, chemical and physical in-use stability has been demonstrated for 3 hours at room temperature.

Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Store in the original package in order to protect from light.

Nature and contents of the container

One pack of 20 multidose vials (type I glass) of 5 ml suspension (10 x 0.5 ml doses) with a stopper (bromobutyl rubber)

Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use. Shake before use.
Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection.
Any unused vaccine or waste material should be disposed of in accordance with local requirements.

NAME AND ADDRESS

Manufacturer

Baxter AG
Industriestrasse 67
A-1221 Vienna
Austria

Distributor

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060

Medicine Classification

Prescription Only Medicine.

Date of Preparation

28 Jan 2010

Questions and answers

Is the monovalent pandemic vaccine a new vaccine

Yes. Pandemic H1N1 influenza is a new influenza strain which emerged in 2009. The pandemic H1N1 influenza vaccine offered in New Zealand is Celvapan® is a monovalent vaccine specific for this strain.

Is this monovalent pandemic vaccine being used in other countries?

Celvapan® has been used in a number of countries national immunisation programmes, including the United Kingdom, Ireland, Germany, Austria, and France.

Does everyone need two doses of the vaccine?

Yes. Each dose is 0.5 mls for children and adults. Doses should be given with a minimum three-week interval.

Is the monovalent pandemic vaccine effective?

Clinical data with Celvapan® demonstrate that, after two doses in 408 adults (including the elderly) and, after the first dose in 146 children and adolescents (aged between six months to 17 years), a comparable efficacy to that observed with seasonal influenza vaccines is achieved.

The vaccine meets all three internationally accepted immunogenicity criteria for influenza vaccines, the data therefore indicate that an adequate immune response is achieved.

For more detailed information, please visit Clinicaltrials.gov. The specific page about the adult trial can be found at: <http://www.clinicaltrials.gov/ct2/show/NCT00959465?term=baxter+h1n1&rank=2>

For more detailed information about the trial in healthy children, please visit Clinicaltrials.gov. The specific page about our trial can be found at: <http://www.clinicaltrials.gov/ct2/show/NCT00976469?term=Baxter+H1N1&rank=2>

What are the benefits of getting the monovalent pandemic vaccine?

Although many pandemic H1N1 influenza cases in 2009 have been mild, evidence has shown serious or fatal health complications for some people who have caught this type of influenza.

Information from other countries shows that the spread of this pandemic H1N1 influenza is not just limited to winter months. Modelling predictions from the pattern seen internationally suggests a resurgence is likely in autumn earlier than influenza is usually experienced with the usual winter influenza season.

For those among the eligible groups the Ministry of Health recommends immunisation as early as possible against the pandemic H1N1 influenza to protect from potential complications.

How does the pandemic H1N1 influenza vaccine work?

The pandemic H1N1 influenza vaccine works in the same way as all other influenza vaccines. Following immunisation it takes approximately two weeks for a good immune response. For further details on influenza vaccines refer to the Immunisation Handbook 2006 Chapter 13 Influenza.

Does this vaccine increase the risk of Guillain-Barré syndrome (GBS)?

There is no reason to expect an increase in the neurological condition called Guillain-Barré Syndrome.

Guillain-Barré Syndrome (GBS) has an annual incidence of around 10–20 cases per one million adults. During the 1970s a swine flu immunisation campaign in the United States an increase in GBS was observed in vaccine recipients (around 1/100,000) and the vaccination campaign was halted. There have not been any further such incidences of an increase in GBS following immunisation with influenza vaccines. Epidemiological studies suggest there is either no increased risk or possibly a slightly increased risk of around 1 per million in adult vaccines). A recent UK study showed the relative incidence of GBS within 90

days of influenza vaccination was not increased, however the risk of GBS within 90 days of an influenza-like illness was seven times higher.⁴

Should individuals get the pandemic vaccine if they have had a flu-like illness in 2009?

Individuals who have had pandemic influenza H1N1 infection can safely be immunised, however immunisation provides no additional benefit in those who have had laboratory confirmed infection. The symptoms of pandemic H1N1 influenza are similar to those caused by other influenza viruses. Most people who have had a flu-like illness do not know whether they have had the specific pandemic influenza H1N1 infection or some other strain. In the absence of a documented laboratory confirmed diagnosis of pandemic influenza H1N1 infection, eligible individuals should be immunised.

Are there any plans for a mass immunisation programme for everyone?

No. Pandemic H1N1 influenza is a mild to moderate illness for most people and most people recover at home without the need for any medical intervention. The Early Protection Programme is designed to protect those people identified as most at risk of complications from pandemic influenza.

When will I be able to get the seasonal influenza vaccine?

The seasonal influenza immunisation programme usually runs from March to June each year. There has been a delay in supply of seasonal influenza vaccine but the Ministry of Health plans to have sufficient supplies to start immunising with seasonal influenza vaccine from 8 March.

This year's seasonal influenza vaccine will contain the pandemic influenza H1N1 strain.

For more information on the seasonal influenza immunisation programme refer to the National Influenza Strategy Group's Influenza Kit and/or website www.influenza.org.nz.

Are people who received Tamiflu® or Relenza® this year, protected from catching the flu?

No, people will still need to be immunised. Tamiflu® and Relenza® are antiviral medicines that may be used to treat an influenza infection if given early in the illness, or to prevent it in some special circumstances during the period when the medicine is taken.

⁴ Stowe J, Andrews N, Wise L, Miller E. 2009. Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenza-like illness using the United Kingdom General Practice Research Database. *Am J Epidemiol* 169(3): 382–8.

Patient information

What Celvapan® is and what it is used for

Celvapan® is a vaccine to protect against pandemic (H1N1) influenza ('swine flu').

Pandemic influenza is a new type of influenza that occurs every few decades and which spreads rapidly around the world. The symptoms of this current type of pandemic are similar to the usual influenza we see each year, but some people can get severely affected by influenza. Because it is a new type of influenza it affects more people, particularly children and young people as they do not have any resistance to this type.

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause influenza.

The Celvapan® vaccine will only be available for a short period from 1 February to offer early protection to frontline health workers and individuals who may be at risk of severe illness if they get pandemic influenza. Most people will obtain protection from pandemic influenza through the seasonal influenza vaccine which will be available from early March.

Celvapan® is available free to individuals 6 months to 64 years with certain health conditions. Please talk to your doctor to see if you or your children are eligible for the free Celvapan® vaccine.

How Celvapan is given

The vaccine will be injected into a muscle (usually in the upper arm).

Doses

Two doses of Celvapan® are given three weeks apart. You will need to come back to the clinic for the second dose three weeks after your first dose.

You can have Celvapan at the same time as other vaccines if necessary.

Pregnancy and breast-feeding

The influenza vaccine is strongly recommended for women who will be pregnant during the influenza season. Pregnant women have been shown to be at increased risk from pandemic H1N1 influenza. They are more likely to develop severe disease or complications compared with women who are not pregnant; the infection may also put the foetus and the newborn at risk.

Celvapan® has been approved for use for pregnant women although specific clinical trials involving pregnant women are not usually carried out for approval.

You should discuss with your vaccinator whether you should receive Celvapan or wait for the seasonal influenza vaccine to be available.

The Celvapan vaccine may be used during breast-feeding.

Egg allergy

Celvapan does not contain egg protein (unlike the seasonal influenza vaccine) therefore people with an egg allergy can have this vaccine.

You should not receive Celvapan

- if you previously had a sudden life-threatening allergic reaction to any ingredient of Celvapan or to any of the substances that may be present in trace amounts as follows: formaldehyde, benzonase, sucrose.

If you are not sure, talk to your doctor or nurse before having this vaccine

In any of these cases, tell your doctor or nurse, as immunisation may not be recommended, or may need to be delayed.

Please inform your doctor or nurse if you have a bleeding problem or bruise easily.

Tell your doctor or nurse

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction to any ingredient contained in the vaccine, to formaldehyde, benzonase, or to sucrose. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if you have a severe infection with a high temperature (over 38°C).
- if you are having a blood test to look for evidence of infection with certain viruses.
- if you have a bleeding problem or bruise easily.

In any of these cases, TELL YOUR DOCTOR OR NURSE, as vaccination may not be recommended, or may need to be delayed.

Possible side effects

As with any vaccine, Celvapan[®] can cause side effects in some people.

Most side effects are mild in nature and short term. The side effects are generally similar to those related to other vaccines. The most frequently occurring side effect is injection site pain, which is usually mild.

Other side effects that may occur are:

- convulsions
- Pain in arms and/or legs
- Flu-like illness
- Swelling of tissue just below the skin.

If any of these side effects occur, please tell your doctor or nurse immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

If I have Celvapan do I still need the seasonal influenza vaccine?

Yes. If you have the Celvapan[®] vaccine you will still need the seasonal influenza vaccine.

While the pandemic H1N1 influenza strain is expected to be the most common influenza strain this year, there may be other strains of influenza circulating. The seasonal influenza vaccine protects against three strains of influenza, including pandemic influenza.

How soon will the vaccine work?

The pandemic H1N1 influenza vaccine works in the same way as all other influenza vaccines. Following immunisation it takes approximately two weeks for a good immune response.

To immunise is your choice

It is your choice whether you accept the offer of early protection with the pandemic vaccine.

You choosing early protection with the Celvapan vaccine (available in February) or the seasonal influenza vaccine (available in March) or both.

Where to go for more information

If you want to know more information about Celvapan please call the Immunisation Advisory Centre on 0800 466 863.

Information for Parents and Guardians

What is Celvapan® and what is it used for?

Celvapan® is a vaccine to protect against pandemic (H1N1) influenza ('swine flu').

Pandemic influenza is a new type of influenza that occurs every few decades and which spreads rapidly around the world. The symptoms of this current type of pandemic are similar to the usual influenza we see each year, but some people can get severely affected by influenza. Because it is a new type of influenza it affects more people, particularly children and young people as they do not have any resistance to this type.

The Celvapan® vaccine will only be available for a short period from 1 February to offer early protection to frontline health workers and individuals who may be at risk of severe illness if they get pandemic influenza. Most people will obtain protection from pandemic influenza through the seasonal influenza vaccine which will be available from early March.

Celvapan® is available free to individuals 6 months to 64 years with certain health conditions. Please talk to your doctor to see if you or your children are eligible for the free Celvapan® vaccine.

Who can have the Celvapan® vaccine and where do they get it?

The Celvapan® vaccine is available free to children with certain health conditions and children under five years who are enrolled in Eligible Practices. Please talk to your doctor to see if your child or guardian may be eligible for the Celvapan® vaccine and where they will need to go to get it.

How is Celvapan given?

The vaccine will be injected into a muscle (usually in the upper arm).

How many doses does my child need?

Two injections of Celvapan given three weeks apart are required. Your child will need to come back to the clinic three weeks after the first injection to get the second one.

Celvapan® is recommended to be given separately from other vaccines.

Celvapan® is an inactivated vaccine and, from experience with influenza vaccine co-administration, it is not expected to have any safety or efficacy concerns. It should, however, be noted that adverse reactions may be intensified if Celvapan® is given with other vaccines.

If other vaccines are needed to be given at the same time the vaccines should be injected into separate limbs and accurately recorded.

Is the Celvapan vaccine safe?

The Celvapan vaccine has been approved for distribution in New Zealand by Medsafe (a division of the Ministry of Health) for people from 6 months of age onwards.

Although there are limited data from clinical studies for the use of the Celvapan® vaccine in children, there are no reasons to doubt the vaccine's safety in children. It has been used for children in overseas pandemic immunisation programmes where the data raise no safety concerns. The Ministry is offering Early Protection immunisation for children under five years because a significant number of young children were hospitalised during the first wave of the pandemic in 2009, particularly those with chronic health conditions.

Celvapan has been used in other countries including the United Kingdom, Ireland, Germany, Austria and France. The reports from these countries show that the safety profile for Celvapan is similar to the seasonal influenza vaccines.

If you would like more information on the safety of the Celvapan vaccine please ask your doctor or call the Immunisation Advisory Centre on 0800 466 863.

Possible side effects from the Celvapan vaccine

As with any vaccine, Celvapan® can cause side effects in some people. Most side effects are mild in nature and short term. The side effects are generally similar to those related to other vaccines. The most frequently occurring side effect is injection site pain, which is usually mild. Other side effects that may occur are:

- convulsions
- Pain in arms and/or legs
- Flu-like illness
- Swelling of tissue just below the skin.

If any of these side effects occur, please tell your doctor or nurse immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

If my child has Celvapan do they still need the seasonal influenza vaccine?

Yes. If you have the Celvapan® vaccine you will still need the seasonal influenza vaccine.

While the pandemic H1N1 influenza strain is expected to be the most common influenza strain this year, there may be other strains of influenza circulating. The seasonal influenza vaccine protects against three strains of influenza, including pandemic influenza.

If your child has had the seasonal influenza vaccine before they will only need one dose, if not they will need two doses.

To immunise is your choice

It is your choice whether you would like your child or guardian to be immunised against pandemic influenza or not.

If you choose to immunise your child or guardian and they meet the eligibility criteria, you have the option of choosing either the Celvapan vaccine (available in February) or the seasonal influenza vaccine (available in March) or both.

What if my child/guardian has had an allergic reaction to a vaccine before?

If your child or guardian has had an allergic reaction to a vaccine or to any ingredients in the Celvapan vaccine (such as formaldehyde, benzonase or sucrose) please discuss with your doctor or nurse before they have the Celvapan vaccine injection.

How do vaccines work?

When a person is given a vaccine, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. It takes about two weeks for the body to produce this protection. None of the ingredients in an influenza vaccine can cause influenza.

Patient consent form

Pandemic Monovalent Vaccine (Celvapan®)

Patient surname _____ Patient first name _____
Phone _____ Date of birth _____ M F NHI _____
Address _____
Your doctor's name/surgery address _____

This is our record that you have given your consent to have the pandemic monovalent vaccine (Celvapan®). Young people aged 16 and above can consent to vaccination.

1. Do any of the following eligibility criteria for a free pandemic monovalent vaccine apply to you? If yes, please tick

- Pregnancy
- Morbid obesity
- Aged between 16 to 64 years with:
 - cardiovascular disease
 - chronic respiratory disease (including asthma if on regular preventive treatment)
 - diabetes
 - chronic renal disease
 - cancer (patient currently has cancer), excluding basal and squamous skin cancers if not invasive
 - other (please specify) _____

2. If any of the following apply to you, then please consult your health care professional

(Please tick) YES / NO

- | | | |
|--|--------------------------|--------------------------|
| Bleeding disorder? | <input type="checkbox"/> | <input type="checkbox"/> |
| Cardiovascular disease? | <input type="checkbox"/> | <input type="checkbox"/> |
| Chronic respiratory disease? | <input type="checkbox"/> | <input type="checkbox"/> |
| Diabetes? | <input type="checkbox"/> | <input type="checkbox"/> |
| Chronic renal disease? | <input type="checkbox"/> | <input type="checkbox"/> |
| Cancer? | <input type="checkbox"/> | <input type="checkbox"/> |
| Guillian-Barré syndrome (paralysis problem)? | <input type="checkbox"/> | <input type="checkbox"/> |

3. Influenza immunisation should not be given to anyone with:

- | | | |
|--|--------------------------|--------------------------|
| Acutely unwell with high fever | <input type="checkbox"/> | <input type="checkbox"/> |
| Severe allergic reaction with respiratory and/or cardiac involvement to any component in the pandemic monovalent vaccine | <input type="checkbox"/> | <input type="checkbox"/> |

4. Possible responses to influenza immunisation

Influenza immunisation is usually well tolerated. Possible responses include redness, tenderness or a hardness at the injection site for a day or two; a mild fever, muscle ache or headache within the first two days. Rarely, an allergic reaction can occur almost immediately. Influenza immunisation is highly effective but cannot guarantee complete protection against catching the pandemic H1N1 (09) influenza strain.

You will be asked to remain under observation for 20 minutes after your immunisation.

I have read or have had explained to me the information on the pandemic monovalent vaccine (Celvapan®), and I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of influenza vaccination.

I understand that this vaccine will only provide protection from the pandemic H1N1 (09) influenza strain.

I understand that I will need two doses of the pandemic monovalent vaccine at least three weeks apart.

I understand getting the vaccine is my choice. I agree to have the vaccine and that it is recommended that I wait here for 20 minutes after the vaccination.

I consent to this information being given to my doctor to update applicable records.

Name of individual: _____

Signature: _____ Date: _____

Immunisation record (for clinic use only)

Celvapan® vaccine – Dose 1

Vaccine batch number: _____ Expiry date: _____ Administered: Left / right arm

Date given: _____ Vaccinator: _____

Celvapan® vaccine – Dose 2

Vaccine batch number: _____ Expiry date: _____ Administered: Left / right arm
Date given: _____ Vaccinator: _____

Parent/Guardian consent form for children

Pandemic Monovalent Vaccine (Celvapan®)

Patient surname _____ Patient first name _____
Phone _____ Date of birth _____ M F NHI _____
Address _____
Your doctor's name/surgery address _____

This is our record that you have given your consent for a person under your guardianship to have the pandemic monovalent vaccine (Celvapan®). Young people aged 16 and above can consent to vaccination.

1. Do any of the following eligibility criteria for a free pandemic monovalent vaccine apply to the patient?

If yes, please tick

- Child aged 6 months to their fifth birthday who is enrolled in an Eligible Practice
- Pregnancy
- Morbid obesity
- Cardiovascular disease
- Chronic respiratory disease (including asthma if on regular preventive treatment)
- Diabetes
- Chronic renal disease
- Cancer (patient currently has cancer), excluding basal and squamous skin cancers if not invasive
- Other (please specify) _____

2. If any of the following apply to the patient, then please consult your health care professional

(Please tick) YES / NO

- | | | |
|--|--------------------------|--------------------------|
| Bleeding disorder? | <input type="checkbox"/> | <input type="checkbox"/> |
| Cardiovascular disease? | <input type="checkbox"/> | <input type="checkbox"/> |
| Chronic respiratory disease? | <input type="checkbox"/> | <input type="checkbox"/> |
| Diabetes? | <input type="checkbox"/> | <input type="checkbox"/> |
| Chronic renal disease? | <input type="checkbox"/> | <input type="checkbox"/> |
| Cancer? | <input type="checkbox"/> | <input type="checkbox"/> |
| Guillain-Barré syndrome (paralysis problem)? | <input type="checkbox"/> | <input type="checkbox"/> |

3. Influenza immunisation should not be given to anyone with:

- | | | |
|--|--------------------------|--------------------------|
| Acutely unwell with high fever | <input type="checkbox"/> | <input type="checkbox"/> |
| Severe allergic reaction with respiratory and/or cardiac involvement to any component in the pandemic monovalent vaccine | <input type="checkbox"/> | <input type="checkbox"/> |

4. Possible responses to influenza immunisation

Influenza immunisation is usually well tolerated. Possible responses include redness, tenderness or a hardness at the injection site for a day or two; a mild fever, muscle ache or headache within the first two days. Rarely, an allergic reaction can occur almost immediately. Influenza immunisation is highly effective but cannot guarantee complete protection against catching the pandemic H1N1 (09) influenza strain.

The patient will be asked to remain under observation for 20 minutes after their immunisation.

I have read or have had explained to me the information on the pandemic monovalent vaccine (Celvapan®), and I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of influenza vaccination.

I understand that this vaccine will only provide protection from the pandemic H1N1 (09) influenza strain.

I understand that I will need two doses of the pandemic monovalent vaccine at least three weeks apart.

I understand getting the patient vaccinated is my choice. I agree to get the patient vaccinated and that it is recommended that we wait here for 20 minutes after the vaccination.

I consent to this information being given to the patient's doctor to update applicable records.

Name of parent/guardian: _____

Signature: _____ Date: _____

Immunisation record (for clinic use only)

Celvapan® vaccine – Dose 1

Vaccine batch number: _____ Expiry date: _____ Administered: Left / right arm
Date given: _____ Vaccinator: _____

Celvapan® vaccine – Dose 2

Vaccine batch number: _____

Expiry date: _____

Administered: Left / right arm

Date given: _____

Vaccinator: _____